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TRANSMIT THE ATTACHED TO

Date: August 4, 2003

Name: Chester T. Barry
Company: U.S. Patent and Trademark Office
Fax: 703.872.9077
Confirming No: 703.306.5921

Name:
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FAX COVER SHEET INFORMATION

From: R. Thomas Payne
Phone: 203.351.4192
Email: tpayne@cl-law.com
Personal Fax: 203.708.3943

Client No.: 207275.0478
Infotext: 5190
Pages including cover sheet: 8
Confirming No.: 203.351.4372

COMMENTS

Examiner Barry:

As discussed, copies of The International Search Report and Written Opinion follow. I certainly appreciate your taking the time to review this matter with me.

Many thanks.

R. Thomas Payne

.StmLib1:1024894.1 08/04/03

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address via the U.S. Postal Service. Thank you.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 207275.0478	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US02/17448	International filing date (day/month/year) 04 June 2002 (04.06.2002)	(Earliest) Priority Date (day/month/year) 04 June 2001 (04.06.2001)
Applicant CUNO, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 1



as suggested by the applicant.



because the applicant failed to suggest a figure.



None of the figures

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/17448

Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

NEW ABSTRACT

Disclosed herein is a multi-layered (1, 2, 3) composite microporous membrane comprising in at least one layer (1) a highly electropositive hydrophilic material distributed throughout wherein the material is capable of irreversibly binding nucleic acid and, optionally, at least one layer (2) where the material is associated with sequence-specific peptide nucleic acids, permitting the simultaneous or sequential capture, amplification and/or identification of specific nucleic acid sequences of interest. Also disclosed herein are methods of use of the composite membranes of the invention in applications based on the sequence-specific capture and/or amplification and identification of nucleic acid from complex biological samples.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/17448

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68

US CL : 435/6

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,527,672 A (MANSFIELD et al.) 18 June 1996, column 1 lines 13-39, column 3 lines 55-60, column 4 lines 38-47, column 9 lines 19-39, column 10 lines 1-3, 11-13	1 - 31



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

17 September 2002 (17.09.2002)

Date of mailing of the international search report

30 SEP 2002

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

Chester T. Barry

Telephone No. 703-308-0651

PATENT COOPERATION TREATY

RECEIVED

MAY 09 2003

CUMMINGS & LOCKWOOD

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITYTo:
DANIEL F. COUGHLIN
CUMMINGS & LOCKWOOD
700 STATE ST., P.O. BOX 1960
NEW HAVEN, CT 06509-1960

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference		Date of Mailing (day/month/year)
207275.0478		05 MAY 2003
International application No.	International filing date (day/month/year)	REPLY DUE
PCT/US02/17448	04 June 2002 (04.06.2002)	within 2 months/days from the above date of mailing
International Patent Classification (IPC) or both national classification and IPC	Priority date (day/month/year)	
IPC(7): C12Q 1/68 and US Cl.: 435/6	04 June 2001 (04.06.2001)	
Applicant		
CUNO, INC.		

- This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:

I	<input checked="" type="checkbox"/>	Basis of the opinion
II	<input type="checkbox"/>	Priority
III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/>	Lack of unity of invention
V	<input checked="" type="checkbox"/>	Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/>	Certain documents cited
VII	<input type="checkbox"/>	Certain defects in the international application
VIII	<input type="checkbox"/>	Certain observations on the international application

DOCKETED MM 5/9/03
 DUE DATE 7/5/03
 STATUTORY DATE _____

- The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
 For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
 For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 04 October 2003 (04.10.2003).

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks

Authorized officer

Chester T. Barry

Received from <203 351 4499> at 8/4/03 2:00:23 PM [Eastern Daylight Time]

WRITTEN OPINION

International application No.

PCT/US02/17448

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-37, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the claims:
 pages 38-42, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the drawings:
 pages 1-17, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.
PCT/US02/17448**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>2-13, 16-20, 22-23, 25, 27-31</u>	YES
	Claims <u>1, 14, 15, 21, 24, 26</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-31</u>	NO
Industrial Applicability (IA)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1, 14, 15, 21, 24, and 26 lack novelty under PCT Article 33(2) as being anticipated by USP 5527672 to MANSFIELD et al. Mansfield describes a method of making a substrate comprising a microporous membrane and a highly electropositive hydrophilic material capable of irreversibly binding one or more sequence-specific nucleic acids operatively positioned on or within the microporous membrane. Mansfield also describes confirming the presence of target nucleic acid derived from animal or vegetable sources in a sample known to include said acid by providing the aforementioned membrane, contacting the sample with the membrane, hybridizing the acid, removing non-hybridized portions, dissociating the acid from PNA, and collecting the acid. See column 1 lines 13 - 39, column 3 lines 55 - 60, column 4 lines 38-47, column 9 lines 19 - 39, and column 10 lines 1 - 3 and 11 - 13.

Claims 2 - 13, 16 - 20, 22 - 23, 25, and 27 - 31 lack an inventive step under PCT Article 33(3) as being obvious over Mansfield. The limitations recited in the dependent claims are within the level of skill evidenced by Mansfield and therefore do not involve an inventive step. See column 1 lines 13 - 39, column 3 lines 55 - 60, column 4 lines 38-47, column 9 lines 19 - 39, and column 10 lines 1 - 3 and 11 - 13.

Claims 1 - 31 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION

International application No.
PCT/US02/17448

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.